UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,425	11/28/2000	John C. Reed	10412-026	7441

7590   09/17/2002

Laura A Coruzzi
Pennie & Edmonds LLP
1155 Avenue of the Americas
New York, NY   10036-2711

EXAMINER
SCHMIDT, MARY M

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 09/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

	Application No.	Applicant(s)
Advisory Action	09/724,425	REED, JOHN C.
	Examiner	Art Unit	
	Mary M. Schmidt	1635	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 08 August 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may <u>only</u> be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

<u>PERIOD FOR REPLY</u> [check either a) or b)]

a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on <u>08 August 2002</u>. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☒ The proposed amendment(s) will not be entered because:

 (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

 (b) ☐ they raise the issue of new matter (see Note below);

 (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

 (d) ☒ they present additional claims without canceling a corresponding number of finally rejected claims.

 NOTE: *see the response under section 5*.

3.☐ Applicant's reply has overcome the following rejection(s): _____.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

 The status of the claim(s) is (or will be) as follows:
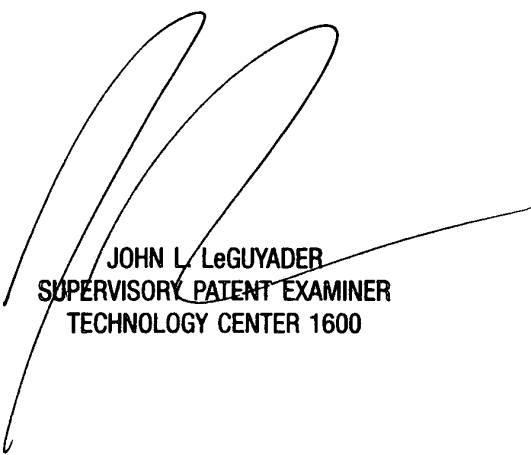
 Claim(s) allowed: _____.

 Claim(s) objected to: _____.

 Claim(s) rejected: *1-12,14,15,17 and 19-28*.

 Claim(s) withdrawn from consideration: _____.

8.☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☐ Other: _____

Continuation of 5. does NOT place the application in condition for allowance because: The priority for instant SEQ ID NO:17 has been confirmed back to the 07/840,716, filed 02/21/1992, which is a FWC parent of 08/271,082 (therefore, the specification of this Application was reviewed). Since neither the instant specification nor the parent specification teaches admistration of SEQ ID NO:17 to a whole organism for therapeutic uses, the claims have been rejection under 35 U.S.C. 112, first paragraph, lack of enablement. Applicants submitted references that provided a teaching of success of SEQ ID NO:17, the same sequence as the Genta Augmerosen G3139 sequence, having utility in whole organisms for the claimed therapeutic uses. However, while the teaching of this one antisense oligonucleotide may have proven utility in vivo, the evidence of success of this one oligonucleotide does not provide equivalent expectation of success for other oligonucleotides to bcl-2 as broadly claimed. Therefore, the claims remain rejected under 35 U.S.C. 112, lack of enablement for use of any bcl-2 anticode oligomer to treat cancer as broadly claimed for the same reasons of record cited in the previous Official Actions mailed 2/28/02 and 7/03/01. The Branch and Flanagan references were previously cited to teach the unpredictability known in the art of design and adminstration of antisense oligonucleotides to whole organisms for treatment effects. Branch specifically taught on page 50, last two sentences, that "[b]ecause non-antisense effects are not currently predictable...[t]hese effects must be explored on a case-by-case basis.".

JOHN L. LeGUYADER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

2